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ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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March 29, 2016

The Honorable Sylvia M. Burwell
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Burwell,

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce is examining U.S. public health preparedness and response to the Zika virus. On March 2, 2016, the Subcommittee on Oversight and Investigations held a hearing on the U.S. public health response to the Zika virus. Thank you for the Department's participation in this hearing.

During the hearing, Members raised questions and concerns about the Federal government's response thus far. The current status of diagnostic testing for Zika is alarming. The most widespread of the tests—which measures the presence of the virus in the blood—only works if administered within five to seven days of the onset of symptoms. Given that nearly 80 percent of individuals infected with Zika appear to be asymptomatic, this test is insufficient for most people who will become infected with Zika. The MAC-ELISA test, which tests for Zika antibodies after the virus has cleared the blood, cross-reacts with a number of other flaviviruses, creating false positives. The most advanced test, the PRNT test, which is used to measure virus-specific antibodies, can distinguish Zika antibodies from those of dengue, yellow fever, or other similar viruses, but has been described by the Centers for Disease Control and Prevention (CDC) as "cumbersome." It is unclear whether there are any laboratories in the U.S., other than the one at CDC, that can perform the PRNT test, and it is unknown how many CDC staff are trained to use the PRNT test.

According to the Census Bureau, in June 2012, 75.4 million women of childbearing age lived in the United States.[1] Many of these women reside in areas with established populations of *Aedes aegypti* mosquitos; even more live in the larger area of the country with established populations of *Aedes albopictus* mosquitoes. Last year, approximately 500,000 pregnant women traveled to other countries or territories with currently local Zika transmission.[2] A further 36,000 pregnant women are currently living in Puerto Rico.[3] Given the current state of the diagnostic tests for Zika, we are concerned that the United States lacks the capacity to test all pregnant women that travel to or live in areas with local Zika virus transmission.

As part of the Committee's work, we have also been examining the Administration's request for an emergency supplemental appropriation to respond to the Zika virus. This request would, in part, provide $1.5 billion to the Department of Health and Human Services, to be divided amongst the CDC, the National Institutes of Health, the Food and Drug Administration, the Centers for Medicare and Medicaid Services, and the Department itself. While the Administration's February 22, 2016 request provided some detail about the appropriations request, the Committee needs more information to consider the adequacy of the Administration's request.

To assist the Subcommittee's examination of these and other related issues, please respond to the following questions as well as provide a detailed briefing on the Department's emergency supplemental request, including its component agencies' portion, by April 12, 2016:

1. Who has been designated as the lead Federal official for the Federal government's response to the Zika virus, pursuant to the Pandemics and All Hazards Preparedness Act (PAHPA)?

2. There are currently no commercially available diagnostic tests for Zika virus. How is the Department working with other Public Health Emergency Medical Countermeasures Enterprise partners to ensure public-private partnerships and incentivize private companies to produce medical countermeasures (MCM), including diagnostics, vaccines, and therapeutics, against Zika?

3. Please provide a detailed description of the three diagnostic tests used for the Zika virus. As part of your response, please include information on:

    a. The procedures and amount of time necessary to complete each test;
    b. The current overall capacity to test for the Zika virus in the United States, including U.S. territories;

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[1] U.S. Census Bureau, Economics and Statistics Administration, U.S. Department of Commerce, Fertility of Women in the United States: 2012, https://www.census.gov/content/dam/Census/library/publications/2014/demo/p20-575.pdf (July 2014).

[2] H. Comm. on Energy & Commerce, Subcomm. on Oversight & Investigations, *Examining the U.S. Public Health Response to the Zika Virus*, 114th Cong. (Mar. 2, 2016) (written statement of Dr. Thomas Frieden, Director, Centers for Disease Control and Prevention).

[3] *Id.*

c. How the Department plans to increase this capacity in the coming months, particularly as we approach the season when local transmission of Zika in the United States becomes more likely;
d. Whether the capacity for diagnostic testing is sufficient to meet levels of demand, particularly among pregnant women; and
e. How many CDC staff are currently trained and performing PRNT tests for the Zika virus.

4. What is the current status of research into more advanced diagnostic testing for the Zika virus, not discussed above, and what hurdles impair the creation of faster and more accurate diagnostic tests for the Zika virus? Please provide a description of any research undertaken or funded by the Department.

5. Please provide a description of current research undertaken by or funded by the Department into the following:

a. Any potential vaccines for the Zika virus;
b. Any potential therapeutics for the Zika virus;
c. The link between Zika virus infection and microcephaly or other birth defects in infants; and
d. The link between Zika virus infection and Guillain-Barré syndrome or other side effects in infected individuals.

6. Currently, States may use some of the grant money they receive from the CDC through the Epidemiology and Laboratory Capacity grant program for vector control activities.

a. What types of vector control methods can States employ when using ELC grant funds?
b. What restrictions does the Department or its components place on the use of these funds for vector control?
c. Does the Department administer any other grant programs, at present, providing funding to States for vector control?

7. How is your Department coordinating with the U.S. Department of Agriculture (USDA) on vector control research to close any gaps and prevent unnecessary duplication?

8. Can States utilize funds received through Public Health Emergency Preparedness grants or the Hospital Preparedness Program grants to respond to the Zika virus? If so, what conditions are placed upon the use of those funds?

9. Please provide a description of any other currently available Department resources that States and localities can use immediately to combat the Zika virus.

10. How is the Department coordinating with the Department of Defense to conduct research and development of MCMs for the Zika virus?

11. To what extent is Health and Human Services working with the Department of the Interior and USDA to understand (1) the role animals, including wildlife, companion, and food animals could play in the amplification and spread of the disease and (2) any efforts the departments may have underway to control diseases of this nature?

If you have any questions regarding this request, please contact Sam Spector or Jen Barblan with the majority committee staff at (202) 225-2927.

Sincerely,

Fred Upton
Chairman

Tim Murphy
Chairman
Subcommittee on Oversight
and Investigations